UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* ARASH MOHAJER and CHRISTOPHER C. PETERSON, Plaintiffs, v. OMNICARE, INC. and CVS HEALTH CORP., Defendants.	Case No. 17-CV-4176 (CM)
UNITED STATES OF AMERICA, Plaintiff, v. OMNICARE, INC. and CVS HEALTH CORP., Defendants.	

MEMORANDUM IN SUPPORT OF OMNICARE'S MOTION TO DISMISS GOVERNMENT'S COMPLAINT-IN-INTERVENTION

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES, RULES, AND REGULATIONS

The Government's False Claims Act case against Omnicare, Inc. ("Omnicare") is based on a fundamental misunderstanding of the long-term-care industry, including the federal and state laws applicable to the pharmacies, like Omnicare, that serve that industry. This leads the Government to assert a wide-ranging fraud where there is none.

The Government claims that Omnicare improperly refilled prescriptions for residents of some types of long-term-care facilities without first obtaining documentation that the prescriptions remained valid. The Government admits that for residents of some facilities—namely "skilled nursing facilities" or "SNFs"—it is appropriate for pharmacies to refill prescriptions based on standing "medication orders" that do not include a set quantity or number of refills. But the Government alleges that such continuing orders are impermissible for residents of all other types of long-term-care facilities, which the Government lumps together as "assisted living facilities" or "ALFs." On the face of the Government's Complaint, the allegations cannot bear the weight of this legal theory. The Government does not identify any nationwide set of rules for prescription-dispensing, much less rules that distinguish so sharply between "SNFs" and "ALFs." An examination of the state laws on the subject reveals that many states specifically permitted Omnicare's alleged conduct of refilling prescriptions at long-term-care facilities other than SNFs. The Complaint therefore does not sufficiently allege that Omnicare submitted "false" claims, an essential element of the False Claims Act.

The Government's claims fail for other reasons as well. *First*, the Complaint's allegations are far overbroad, sweeping in Omnicare pharmacies, timeframes, and federal programs for which the Government has no basis to allege fraud, much less with the specificity that Rule 9(b) requires. *Second*, regarding the essential element of scienter, the Government alleges merely that Omnicare's automated and human checks on prescription documentation

could have been designed more effectively to screen out the allegedly "invalid" refills. Fraud under the False Claims Act requires far more than system imperfections.

Finally, the Government's follow-on claims for reverse false claims, unjust enrichment, and payment by mistake all fail for these and other, claim-specific, reasons.

BACKGROUND[1]

Omnicare operates "approximately 160 pharmacies in 47 states," "dispens[ing] tens of millions of prescription drugs" to "well over one million patients" annually. Dkt. No. 34 (Complaint-in-Intervention) ¶ 4, 20 ("Gov't Compl."). These patients reside in thousands of different long-term-care facilities, which provide different types of services for varying medical conditions. Each Omnicare pharmacy follows the relevant state's law governing the dispensing of medications to the particular long-term-care facility. The Government's allegations are premised on two fundamental beliefs: (1) all long-term-care facilities may be neatly classified into two categories (skilled nursing homes and everything else), and (2) the state laws governing dispensing of prescription medication are uniform. Neither belief is well-founded.

A. A Wide Range of Long-Term-Care Facilities Exist to Provide Personal and Medical Services to Residents Depending upon Their Conditions.

To serve the various needs of elderly, disabled, and rehabilitating patients, the long-term-care industry has developed facilities that serve patients with needs that range from 24-hour, hospital-like care, to assistance with just a few daily tasks, and everything in between. While some facilities offer independent living, *id.* ¶ 75, many other facilities provide care and supervision for residents "who require assistance with daily activities such as bathing, dressing, and using the bathroom." *Id.* ¶ 77. Such residents generally "have access to many services," including "help with medications," "24-hour supervision," and "on-site staff." *Id.*

[1] Omnicare's recitation of the Complaint's allegations is not an agreement that they are true.

SNFs, which "typically provide nursing care 24 hours a day and regular physician care," provide the greatest level of long-term medical care. *Id.* ¶ 72. Many SNFs function essentially as hospitals, "providing skilled medical care," with a "designate[d]" medical director, and availability of "laboratory services as well as radiology and other diagnostic services for patients." *Id.* ¶ 73. SNFs often "are located within larger communities that offer other types of long-term care," including "different units or wings that offer different levels of medical care" and permit "residents to move to different levels of assistance and medical care as their needs change over time." *Id.* ¶ 78.

For all facilities other than SNFs, the Government collapses the entire spectrum of care into what it calls ALFs. *Id.* ¶¶ 13, 74–88. This dichotomy—with ALFs being facilities whose "principal purpose is to provide housing in conjunction with personal care and social services, rather than continuous skilled medical care," *id.* ¶ 79—does not match industry reality. The gradations between medical care in SNFs and other facilities vary by facility and are not subject to bright lines. Even the Government couches its descriptions of ALFs in generalities and caveats, *e.g.*, *id.* ¶ 13 (stating that ALFs "***generally*** do not have physicians ***on staff*** to oversee and monitor residents' drug therapy" (emphasis added)). And the Government's own source says only that SNFs "focus on medical care ***more*** than ***most*** assisted living facilities." National Institute on Aging, *Residential Facilities, Assisted Living, and Nursing Homes*, (May 1, 2017), https://www.nia.nih.gov/health/residential-facilities-assisted-living-and-nursing-homes (emphasis added). That residents of ALFs may require significant medical oversight and assistance is no surprise: Residents are predominantly over the age of 75 years, "most . . . suffer from chronic health conditions," including nearly half with Alzheimer's disease, and one third with heart disease. Gov't Compl. ¶¶ 84–87.

B. Legal and Contractual Requirements for Prescriptions Dispensed to Residents of Long-Term-Care Facilities Vary Widely.

In dispensing medications for residents of long-term-care facilities, long-term-care pharmacies like Omnicare must operate under the requirements of a variety of insurance plans (including commercial insurance, Medicare Part D, Medicaid, and Tricare), as well as the laws of the state where each pharmacy is located. Because of the medical oversight many long-term-care facilities provide, requirements for dispensing medication to their residents may differ from the requirements for traditional walk-in pharmacies. In most states, long-term-care pharmacies may dispense medications not only pursuant to a traditional written prescription, but also based upon a prescriber's "medication order," akin to the method used for patients in hospitals. What constitutes valid prescription documentation varies by state and by insurance plan.

1. Federal Healthcare Program Requirements Differ Concerning When Prescription Medication Is Reimbursable.

The Government premises its case on the proposition that there is one federal standard for the documentation required to make a prescription drug reimbursable under all federal health care programs. *See id.* ¶ 89. To the contrary, Medicare Part D guidance regarding the relevant requirements evolved during the time period at issue, and the Government points to no such requirements of any kind under Medicaid or Tricare.

The Medicare Part D regulatory provisions the Government cites currently provide coverage for prescription drugs "dispensed upon a valid prescription," 42 C.F.R. § 423.104(h), and define that term by reference to "applicable State law requirements constituting a valid prescription," *id.* § 423.100. But both the limitation on coverage and the reference to state law first took effect on January 1, 2013—three years into the "Relevant Period" for this case. Gov't Compl. ¶ 1; *see* Medicare Program; Changes to the Medicare Advantage and the Medicare

Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes, 77 Fed. Reg. 22,072 (Apr. 12, 2012).

As to Medicaid and Tricare, the Government does not identify any statutory or regulatory provision describing the documentation required for a prescription to be reimbursable. It claims that 42 U.S.C. § 1396d(a)(12) dictates that "Medicaid coverage . . . does not include drugs dispensed pursuant to invalid prescriptions," Gov't Compl. ¶ 45, but that provision merely states that Medicaid may cover "prescribed drugs," with no definition of the term, the required documentation, or reference to any state law. The Government cites nothing that purportedly guides the requirements for reimbursement under Tricare. *See id.* ¶¶ 60–65.

2. State Laws and Regulations Differ in Their Requirements for Dispensing Prescriptions to Residents of Long-Term-Care Facilities.

Even under the Government's view that, at all times, all federal programs would reimburse only upon examination of state law, the relevant state laws varied widely.

At SNFs, as the Government agrees, prescription drugs may be dispensed based upon medication orders that "do not typically specify the total quantity prescribed or the number of refills authorized." *Id.* ¶ 99. Such orders thus "continue . . . until the facility's attending physician discontinues the order." *Id.* The Government purports to draw a hard line between SNFs (where such practices are permitted) and all other facilities (where the Government claims they are not), but it admits that state law varies. *See* Gov't Compl. ¶ 90.

In fact, many states allow the use of medication orders in an array of long-term-care facilities. *See, e.g.*, Minn. Stat. § 151.01(16b) (allowing use of "chart order" prescriptions—which need not include the quantity prescribed—"during the patient's stay in a hospital ***or long-term care facility***" (emphasis added)); N.J. Code Ann. § 13:39-9 ("'Medication order' means a written request for medication originated by a practitioner and intended for patient use in the

health care facility." (emphasis added)). State laws permit medication orders in a range of facilities, including "assisted living center[s]," "assisted living program[s]," "extended care facilit[ies]," "facilit[ies]," "long-term-care facilit[ies]," "health care institution[s]," "health facilit[ies]," "health care facility[ies]," "institutional facility[ies]," "institution[s]," "licensed medical care facilit[ies]," "medical facilit[ies]," and "rest homes with nursing supervision." Ex. 1 (State-Law Chart).[2] These terms, moreover, are defined in myriad ways (when they are defined at all) across the states. *See id.*[3]

C. Omnicare's Operations for Filling Prescriptions.

During the relevant time period, each Omnicare pharmacy operated on one of two computer systems that tracked and managed the prescription-dispensing process: OmniDX or Oasis. Gov't Compl. ¶ 121. For either system, when a new prescription was received, a pharmacy technician was tasked with "enter[ing] the prescription information." *Id.* ¶ 123. This information would also be reviewed by a pharmacist. *Id.* ¶ 125.

Each system had a setting that would determine whether a number of refills or prescribed quantity was "required" to be entered. *Id.* ¶ 135. If that setting, the Retirement field in OmniDX or the prescribed quantity required field in Oasis, was set to "Y", pharmacy staff had to manually

[2] Exhibit 1 is a chart of state laws, which is not intended to be comprehensive, and includes only states for which claims have been brought or which are otherwise clearly associated with the claims the Government has identified in its Complaint. In addition to the statutory and regulatory provisions discussed in the chart, pharmacy dispensing is subject to guidance by, among other things, state boards of pharmacy and other sub-regulatory guidance, payer guidelines, and standards of pharmacy practice.

[3] The Government quotes, divorced from context, statements attributed to a handful of Omnicare employees between 2012 and 2015 as evidence that Omnicare agreed with the Government's legal theory that SNFs and ALFs are clearly distinct in all states. *See* Gov't Compl. ¶¶ 188–195. In fact, those quotes, which could not overrule the plain language of the varying state laws, speak in generalities, referring to how "most states" work, providing a "rule of thumb," and describing the kinds of facilities that require prescriptions to include refills at a high level such as "assisted living and [facilities for the developmentally disabled]." *Id.* (alteration in original).

enter a number for the amount of refills allowed or the total quantity prescribed and "the system would not process the prescription for dispensing unless" a number was entered. *Id.* ¶¶ 128–130; 137. The systems then tracked "how many times the prescription should be filled and when the prescription expired," to "ensur[e] that the pharmacy did not dispense more drugs to patients than the treating physician had prescribed." *Id.* ¶¶ 123, 124. Once all refills were exhausted, the systems prevented any additional dispensing. *Id.* ¶¶ 131, 137.

If, however, it was permissible to "refill the drugs indefinitely without a new prescription from the patient's physician," *id.* ¶ 122, the relevant field was set to "N," and additional dispensing could occur "if no prescribed quantity was manually entered" by the pharmacy technician or reviewing pharmacist. *Id.* ¶ 138.

Pharmacies could also refill medications via "cycle fill," meaning that many prescriptions for residents of a long-term-care facility could be filled for simultaneous delivery. *Id.* ¶ 139. "[P]rior to each periodic cycle fill delivery," staff at the long-term-care facility were expected "to review a report sent from the Omnicare pharmacy listing the medications the pharmacy intended to dispense," "to make any necessary changes and return a signed authorization form to the pharmacy." *Id.* ¶ 171. Absent such a form, Omnicare instructed, "the pharmacy does not have permission and should not dispense any cycle fill medications." *Id.*

D. The Government's Theories of Liability.

The Government makes no allegation that *any* Omnicare employee was *ever* instructed to dispense or refill medication based on invalid prescriptions or to disregard the automated processes that were designed to prevent such dispenses. Nor does the Government allege that any patient ever received a medication that was not actually needed.[4] Instead, the Government

[4] Similarly, the Government claims the conduct it alleges "exposed [patients] to a significant risk of harm," but does not allege any patient was actually harmed. *See* Gov't Compl. ¶¶ 234–237.

faults Omnicare's computer and human checks, and argues that Omnicare submitted false claims for payment under three distinct allegedly fraudulent schemes:

OmniDX: The Government claims that Omnicare knowingly submitted claims for reimbursement that were based on invalid, non-reimbursable prescriptions because Omnicare did not provide enough "training on the import of the Retirement field" in OmniDX. *Id.* ¶ 153.[5] Instead of relying on local employees to use their knowledge of local law and the facilities they serviced to decide how the Retirement field should be coded, the Government wishes Omnicare had created a "standardized process to properly set up facilities in OmniDX." *Id.* ¶ 154.

Cycle Fill: The Government claims that "pharmacy staff routinely failed" to check the OmniDX cycle-fill orders, and that certain Omnicare pharmacies delivered cycle-fill orders without receiving authorization forms from the facility. *Id.* ¶¶ 165, 172.

Oasis: The Government purports to bring a separate theory about improper dispensing by Omnicare pharmacies using the Oasis system, but the Complaint recites only (A) a conclusory assertion that 510 facilities were improperly coded in Oasis, and (B) two alleged statements by pharmacists from two individual pharmacies who believed the Oasis system did not "reliably distinguish between skilled and unskilled facilities and that medications for ALF residents were sometimes processed as SNF orders." *Id.* ¶¶ 158–161.

ARGUMENT

I. THE COMPLAINT DOES NOT STATE A CLAIM UNDER THE FALSE CLAIMS ACT

Counts I and II of the Complaint bring claims for violations of §§ 3729(a)(1)(A) and (a)(1)(B) of the FCA. *See* Gov't Compl. ¶¶ 272–282. To plead a claim against Omnicare under

[5] The Government also faults Omnicare for not providing enough training on what it terms "the requirement to consistently designate unskilled facilities as retirement facilities," Gov't Compl. ¶ 153, but as discussed this is simply not reflective of the law across the states. *See supra* at 5–6.

§ 3729(a)(1)(A), the Government must allege that: "(1) there was a false or fraudulent claim, (2) the defendant knew it was false or fraudulent, (3) the defendant presented the claim, or caused it to be presented, to the United States, and (4) it did so to seek payment from the federal treasury." *United States ex rel. Kester v. Novartis Pharms.*, 23 F. Supp. 3d 242, 252 (S.D.N.Y. 2014). Similar elements apply to the claim under § 3729(a)(1)(B). *See id.* Furthermore, claims under both provisions are subject to Federal Rule of Civil Procedure 9(b). *See United States ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 81 (2d Cir. 2017).

The Government's claims under these provisions are defective in three ways. *First*, the Complaint does not allege facts showing that the prescription claims about which it sues were "false." *Second*, the Complaint fails to plead its theories with the particularity demanded by Rule 9(b) and the FCA. *Third*, the Complaint does not sufficiently allege that Omnicare acted "knowingly."

A. The Complaint Does Not Sufficiently Plead That Omnicare Submitted "False or Fraudulent" Claims.

The Government's claims under §§ 3729(a)(1)(A) and (a)(1)(B) require allegations that Omnicare submitted claims for payment that were "false." *See Kester*, 23 F. Supp. 3d at 252. Where an FCA plaintiff "fails to point to a federal regulatory requirement" supporting its theory of falsity, its claims are not viable. *United States ex rel. Crews v. NCS Healthcare*, 460 F.3d 853, 858 (7th Cir. 2006). And falsity must be alleged as to the specific allegedly improper claim for payment, not the overarching scheme. *See United States v. Teva Pharms.*, 2016 WL 750720, at *13 (S.D.N.Y. Feb. 22, 2016) ("'The [FCA] attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment,'" (quoting *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995))). The Complaint fails this test in its entirety because it does not allege legal support for its nationwide theory of falsity, and many of

the state-law prescription requirements the Government would incorporate permitted Omnicare's alleged conduct.

1. The Government's Nationwide Theory of Falsity Is Baseless.

The Government's theory of falsity is that Omnicare submitted claims that did not comply with "applicable State law requirements constituting a valid prescription," 42 C.F.R. § 423.100, and that these requirements made Omnicare's alleged conduct illegal nationwide, *see* Gov't Compl. ¶ 89. The Government further applies this theory to all prescription claims at issue in this case—under Medicare Part D, Medicaid, and Tricare. *See id.* But, the sole regulation on which the Government bases this nationwide theory applies to Medicare Part D only and did not come into effect until January 1, 2013—three years into the "Relevant Period" for this case of 2010 to 2018.[6] *See supra* at 5–6.

Absent any federal-law basis for falsity, the Government cannot support a nationwide theory of falsity based on alleged violations of ***state*** law. While the Complaint alleges that Omnicare expressly certified its compliance with federal law, there is no suggestion that Omnicare ever expressly certified compliance with any ***state*** prescription laws. *See* Gov't Compl. ¶ 38 (alleging that subcontracts between Part D Plans and pharmacies "obligat[e] the entity to comply with all applicable ***federal*** laws, regulations and CMS instructions" (emphasis added)). Nor does the Complaint state a theory of "implied" false certification regarding state law, which applies "where 'a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements . . . render[ing] the . .

[6] Those provisions were added at that time because of concerns that Medicare Part D needed "to remove any doubt as to the appropriate source of law to consult when determining whether a prescription is valid." Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes, 77 Fed. Reg. 22,072 at 22,139 (Apr. 12, 2012).

. representations misleading.'" *United States ex rel. Grubea v. Rosicki, Rosicki & Assocs.*, 318 F. Supp. 3d 680, 699 (S.D.N.Y.), *reconsideration denied*, 319 F. Supp. 3d 747 (S.D.N.Y. 2018) (alterations in original) (quoting *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1999 (2016)). The Complaint does not identify any representation that Omnicare made about its compliance with state prescription laws.

Accordingly, the Government's claims should be dismissed except insofar as they relate to Medicare Part D during the 2013–2018 time period.

2. Many States Permitted Omnicare to Dispense to Long-Term-Care Facilities Based on Medication Orders Without a Defined Number of Refills or Total Quantity.

The Government's theory of nationwide falsity also fails for the independent reason that the state prescription laws do not uniformly prohibit what Omnicare allegedly did. On the contrary, most of the states about which the Government sues ***permit*** pharmacies to dispense based on medication orders without a defined number of refills or total quantity.

The Complaint concedes that medications for residents of SNFs may be dispensed based upon medication orders that "do not typically specify the total quantity prescribed or the number of refills authorized," and they "continue . . . until the facility's attending physician discontinues the order." Gov't Compl. ¶ 99. It also agrees that state law varies as to what is permitted in other types of facilities. *Id.* ¶ 90. In fact, many states do not draw ***any*** line between SNFs and other long-term-care facilities for purposes of these prescription documentation guidelines. *See, e.g.*, Minn. Stat. § 151.01(16b) (allowing use of "chart order" prescriptions—which need not include the quantity prescribed—"during the patient's stay in a hospital ***or long-term care facility***" (emphasis added)).

State laws define in various ways the facilities where it is permissible to dispense on medication orders that do not specify the quantity prescribed or number of refills. *See* Ex. 1

(State-Law Chart).[7] Some states describe the facilities in which such orders are permitted using terms that, on their face, include the "ALF" facilities that the Government claims are excluded. *See* Colo. Rev. Stat. § 12-42.5-102(24)(b) ("long-term care facility"); Md. Code Regs. § 10.34.36.02 ("assisted living program"); Minn. Stat. § 151.01(16b) ("long-term care facility"); Neb. Rev. Stat. Ann. § 38-2810 ("long-term care facility"); Okla. Stat. Ann. tit. 59, § 353.1 ("assisted living center"); S.C. Code Ann. § 40-43-30 ("extended care facility"); Va. Code Ann. § 54.1-3408.01(A) ("long-term-care facility"); Wash. Code Rev. § 18.64.550 ("long-term care facility"); Wyo. Admin. Code 059.0001.15 § 4 ("LTCF"). Other states use terms that sweep even more broadly. *See* Conn. Agencies Regs. § 19-13-D8v(b)(5) ("rest homes with nursing supervision"); Idaho Code Ann. § 54-1705(11) ("institutional facility"); Ind. Code § 25-26-13-2 ("health care institution"); Iowa Admin. Code r. 657-23.2(155A) ("facility"); Kan. Stat. Ann. § 65-1626 ("medical care facility"); La. Stat. Ann. § 37:1164 ("institutional facility"); 105 Code Mass. Regs. § 700.001 ("health facility"); Mich. Comp. Laws Ann. § 333.17708 ("health facility"); Mont. Admin. R. 24.174.831 ("facility"); Nev. Admin. Code 639.442 ("medical facility"); N.J. Admin. Code § 13:39-9 ("health care facility"); N.Y. Comp. Codes R. & Regs. Tit. 8, § 29.7 ("health care facility"); 21 N.C. Admin. Code § 46.1414 ("health care facility"); 49 Pa. Code § 27.1 ("institution"); Vt. Code Regs. 04-030-230 §§ 11.2(a), 11.26 ("institutional facility"); 22-B D.C. Mun. Regs. §§ 1999, 1999.1 ("institutional facility"). These terms, moreover, are defined in myriad ways across the states, but all of them underscore that "ALFs" are covered. *See* Ex. 1 (State-Law Chart). In Delaware, Indiana, New York, and South Carolina, the term used to describe which facilities may utilize such prescriptions is wholly undefined,

[7] To the extent there is any need to take judicial notice of the matters contained in the various state statutes and regulations, the Court may do so. *See Christman v. Skinner*, 468 F.2d 723, 726 (2d Cir. 1972) ("proper" to "take judicial notice of . . . regulations").

although closely related terms are defined in ways that encompass "ALFs." *See id.* Finally, in Illinois, Iowa, Massachusetts, New Jersey, Ohio, Vermont, and Washington, the definitions refer back to an analysis of each long-term-care facility's specific licensing status with state agencies. *See id.*

Contrary to the Government's assertion, Gov't Compl. ¶ 94, these states also permit pharmacies to honor prescriptions for residents of long-term-care facilities for more than one year from the date the order was written. Unlike traditional written prescriptions a patient may obtain from her doctor—which are issued by the doctor a single time—continuing medication orders are renewed each time a doctor reviews the patient's chart. But even if the rules for traditional written prescriptions the Government cites did apply, many states allowed prescriptions to be used for longer time periods. *See* 24 Del. Code Regs. § 2500-1.0 (until "stop date . . . established by an appropriate authority"); Idaho Admin. Code r. 27.01.01.117 ("fifteen (15) months"); 225 Ill. Comp. Stat. Ann. § 85/3 ("15 months"); Iowa Code Ann. § 155A.29 ("eighteen months"); Kan. Admin Regs. § 28-39-156 ("in accordance with written policies of the facility"); N.J. Admin. Code § 13:39-9.11 (following "written policies of the facility"); N.M. Ann. Code § 7.8.2.35 (until doctor gives "specific orders" to stop); S.C. Code Ann. Regs. § 61-17-1302 ("in accordance with facility policies and procedures"); Wash. Rev. Code § 18.64.570 (until chart order is "discontinued"); Wyo. Stat. Ann. § 33-24-101 ("two years").

The Government cannot bring an FCA claim premised on alleged violations of state prescription requirements in any of these states. It is axiomatic that "[c]laims are not 'false' under the FCA unless they are furnished in violation of some controlling rule, regulation or standard." *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1026 (D. Nev. 2006); *see also United States ex rel. Glass v. Medtronic, Inc.*, 957 F.2d 605, 608 (8th Cir. 1992) (affirming grant of

summary judgment after concluding that the defendant's actions were "proper" under the applicable Medicare provision and therefore "not false or fraudulent"). And even if the Court were to interpret any of these state-law requirements differently from Omnicare, the requirements were, at a minimum, susceptible to a reasonable interpretation that dispensing was permissible based on medication orders. This ambiguity would foreclose an FCA claim because "the FCA does not reach . . . claims made based on reasonable but erroneous interpretations of a defendant's legal obligations." *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 287–88 (D.C. Cir. 2015)

B. The Complaint Fails to Plead Particular False Claims.

Because both § 3729(a)(1)(A) and (a)(1)(B) require false "claims," the Government must "plead with particularity that false claims were actually submitted to the government." *Kester*, 23 F. Supp. 3d at 252. The Second Circuit "has 'rigorously' enforced" this pleading requirement. *United States ex rel. Gelbman v. City of New York*, 790 F. App'x 244, 247 (2d Cir. 2019). Accordingly, "a plaintiff cannot circumscribe the Rule 9(b) pleading requirements by alleging a fraudulent scheme in detail and concluding, that as a result of the fraudulent scheme, false claims must have been submitted." *Kester*, 23 F. Supp. 3d at 253 (internal quotation marks omitted). Rather, the Government "must plead both the particular details of a fraudulent scheme and 'details that *identify particular false claims for payment* that were submitted to the government.'" *Id.* at 255 (quoting *United States ex rel. Karvelas v. Melrose–Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir. 2004)). The Government fails to do so in three ways: (1) it does not plead its "Oasis theory" with particularity; (2) it does not include particular allegations supporting the expansive timeframe about which it sues; and (3) it does not plead any of its theories with particularity as to the Medicaid and Tricare programs.

1. Oasis Theory

The Government's Oasis theory, *see supra* at 8, is pleaded only in the vaguest terms. The Complaint asserts that 510 long-term-care facilities were mistakenly coded in Oasis, Gov't Compl. ¶ 158, but the prescriptions it identifies were all dispensed by pharmacies that used the OmniDX system, *see* Exs. 1 & 5 to Gov't Compl. The Government's vague allegations include neither "the particular details of a fraudulent scheme" nor "details that identify particular false claims for payment that were submitted to the government." *Kester*, 23 F. Supp. 3d at 255 (internal quotation marks omitted).

To be sure, there are circumstances under which an FCA complaint need not include "details of actual bills or invoices submitted to the government," but that exception applies only where there are allegations "that lead to a strong inference that specific claims were indeed submitted ***and*** that information about the details of the claims submitted are peculiarly within the opposing party's knowledge." *Chorches*, 865 F.3d at 93 (emphasis added). This "ensure[s] that those who *can* identify examples of actual claims *must* do so at the pleading stage." *Id.* at 86. The Government, as the recipient of the claims, has sufficient knowledge to provide examples if any exist, and *Chorches* required it to do so. The Government's failure is "particularly noteworthy" given its direct access to the relevant claims information. *See Gelbman*, 790 F. App'x at 248 (rejecting relator's attempt to evade pleading requirements where relator alleged Medicaid fraud in New York while working "as an Information Specialist working on Medicaid reimbursement at [the New York Department of Health], the agency responsible for submitting Medicaid claims to the federal government"). Given that the Government spent the last 4 years investigating this matter, these failures warrant dismissal of the Oasis theory with prejudice. *See United States ex rel. Crennen v. Dell Mktg. LP*, 711 F. Supp. 2d 157, 164 (D. Mass. 2010) (dismissing with prejudice for failure to plead specific claims with particularity because "after

three years and a government investigation," the relator "still cannot allege" specific false claims).

2. 2010–2011 and 2017–2018

The specific claims that the Government does identify are all from the time period 2012–2016. Though the Complaint purports to cover a nine-year period from 2010 to 2018, Gov't Compl. ¶ 1, it identifies no claims for the years 2010–2011 or 2017–2018.[8] The Government cannot double the timeframe of its Complaint in this manner. Rule 9(b) and the FCA require it to plead "examples of specific false claims submitted to the government" and "the specific examples should cover the relevant time period in order to ensure that defendants have adequate notice of the charges against them to prepare a defense." *United States v. Comstor Corp.*, 308 F. Supp. 3d 56, 92 (D.D.C. 2018) (internal quotation marks omitted) (dismissing where relator provided "no additional information on sales from before September 2008"); *see also United States ex rel. Seal 1 v. Lockheed Martin Corp.*, 429 F. App'x 818, 820 (11th Cir. 2011) (per curiam) (affirming dismissal of portion of claim relating to four-year period in which a relator "does not allege the amount of the claims, the number of claims presented nor dates on when such claims were made").

3. Medicaid and Tricare

Although the Government purports to sue for false claims to Medicaid and Tricare, it does not identify a single Medicaid or Tricare claim submitted pursuant to any of the theories the Government alleges. Nor does it make any allegation that would suggest that such claims likely occurred. The Complaint therefore should be dismissed insofar as it relates to Medicaid and Tricare. *See United States ex rel. Mooney v. Americare, Inc.*, 2013 WL 1346022, at *7 n.6

[8] Regarding the later portion of this time period, the Government actually alleges that the alleged computer-system issues in the OmniDX system were ***fixed*** in 2016. *See id.* ¶¶ 227–229.

(E.D.N.Y. Apr. 3, 2013) ("Because none of the twelve exemplars represent claims made to Medicaid, the exemplars do not provide defendants with notice of any Medicaid claims. Thus, as stated above, the scheme is insufficiently pled as it relates to Medicaid.").

C. The Complaint Does Not Sufficiently Plead That Omnicare Acted "Knowingly."

The False Claims Act requires a showing that the Defendant "knowingly" submitted a false claim or statement. 31 U.S.C. § 3729(a)(1)(A), (a)(1)(B). "Knowingly," under the FCA, is defined to include acting "in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A)(iii). The Supreme Court has made clear that the FCA's intent standard is "rigorous" and must be "strict[ly] enforce[d]." *Escobar*, 136 S. Ct. at 2002. "[T]he requisite intent" under the FCA "is the knowing presentation of what is known to be false as opposed to negligence or innocent mistake." *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 703 (2d Cir. 2001) (internal quotation marks omitted), *abrogated on other grounds by Escobar*, 136 S. Ct. 1989. In FCA cases, the Second Circuit "'ha[s] repeatedly required plaintiffs to plead the factual basis which gives rise to a strong inference of fraudulent intent.'" *United States ex rel. Tessler v. City of New York*, 712 F. App'x 27, 29 (2d Cir. 2017) (quoting *O'Brien v. Nat'l Prop. Analysts Partners*, 936 F.2d 674, 676 (2d Cir. 1991)). The Complaint fails to do so here, and should be dismissed in its entirety.

The Government admits that Omnicare had various systems in place to ensure that prescriptions were dispensed pursuant to valid documentation. *See* Gov't Compl. ¶¶ 121–138. It does not allege that any Omnicare employee intentionally evaded those systems, or that anyone in management told any employee to do so. Instead, the Government complains that Omnicare grew "rapidly" and did not quickly establish the Government's preferred form of "organizational infrastructure." *Id.* ¶ 103.

The FCA's "reckless disregard" standard sets a much higher bar: "Recklessness entails conduct that is 'highly unreasonable and which represents an extreme departure from the standards of ordinary care.'" *Grubea*, 318 F. Supp. 3d at 694 (quoting *Chill v. Gen. Elec. Co.*, 101 F.3d 263, 269 (2d Cir. 1996)). Thus, mere "errors in data collection or recognizing the need for better quality control does not constitute 'reckless disregard' within the meaning of the FCA." *United States ex rel. Kirk v. Schindler Elevator Corp.*, 130 F. Supp. 3d 866, 879 (S.D.N.Y. 2015). The Government's allegations that Omnicare's many systems did not operate flawlessly is not enough because "[t]he mere failure of a system to catch an error does not establish recklessness." *United States ex rel. Hefner v. Hackensack Univ. Med. Ctr.*, 495 F.3d 103, 110 (3d Cir. 2007).

The Government's allegations that Omnicare lacked adequate "formal training" regarding these systems, Gov't Compl. ¶ 111, cannot carry the day, either. Indeed, the Government recognizes that such training *was* in place—it was just conducted at the local level where individuals had direct knowledge of the unique requirements of state law and how each particular facility fit within the relevant state's law. *See id.* ¶ 106. Recklessness does not exist merely because the Government now believes there was a better way to conduct this training. *See United States ex rel. Ervin & Assocs., Inc. v. Hamilton*, 298 F. Supp. 2d 91, 101 (D.D.C. 2004) (argument that defendant should have "install[ed] a system by which concerns . . . were to be routed to the responsible personnel" was "without merit" absent any support "for the proposition that failure to implement proper channels of communication may constitute gross negligence, let alone extreme gross negligence under the False Claims Act"). And even if pharmacy-level staff made mistakes, "[p]roof of reckless disregard requires much more than errors, even egregious errors." *Id.*

Nor can the Government rely on allegations of events occurring in discrete Omnicare pharmacies between August 2012 and 2015 in which prescription-documentation issues were allegedly raised to local Omnicare supervisors. To begin, many of these events are irrelevant as they occurred in states where the law ***permitted*** Omnicare's alleged conduct. *See* Gov't Compl. ¶¶ 200–201, 203–205, 209–210, 213–214, 217, 220 (discussing events occurring in Maryland, Minnesota, New Mexico, North Carolina, Ohio, Pennsylvania, and South Carolina); Ex. 1 (State-Law Chart). The remaining events reflect discrete issues allegedly arising at the individual pharmacy level in a handful of locations, many of which the Government alleges were also resolved at the local-pharmacy level. *See* Gov't Compl. ¶¶ 198–199, 206–207, 216, 218, 221.[9] Many of these events are pleaded in such vague terms that the Government failed its basic obligation "to identify the individuals responsible for making the statements, other than to describe them as employees of the defendants." *United States ex rel. Vallejo v. Investronica, Inc.*, 2 F. Supp. 2d 330, 337 (W.D.N.Y. 1998). The Government speaks in terms of Omnicare "operations managers" or employees with roles related to "compliance," Gov't Compl. ¶¶ 210–211, 216–218, 221, but FCA "pleadings have been found to be insufficient" where they lack any identifying details. *Vallejo*, 2 F. Supp. 2d at 337; *see also United States ex rel. DeCarlo v. Kiewit/AFC Enters.*, 937 F. Supp. 1039, 1050 (S.D.N.Y. 1996) (dismissing FCA case where "the complaint fails to refer to specific employees who may have been involved in submitting false claims").

[9] The Government further relies on alleged statements of Omnicare regional compliance officers related to the development of global computer changes. *See id.* ¶¶ 222–233. Federal Rule of Evidence 407 would bar use of Omnicare's development of these subsequent remedial measures to prove liability.

Regardless, these discrete, local events allegedly occurring in eight of Omnicare's approximately 160 pharmacies cannot establish that Omnicare knowingly engaged in corporate-wide conduct that was "an extreme departure from the standards of ordinary care," *Grubea*, 318 F. Supp. 3d at 694, as required to establish recklessness under the FCA. A theory of nationwide fraud based upon discrete conduct by a few local-level employees would improperly "draw[] no distinction between the knowledge of corporate officers and that of potentially thousands of ordinary employees, including the knowledge of all employees in the collective pool of information imputed to the corporation." *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1275 (D.C. Cir. 2010) (internal quotation marks omitted); *see also United States ex rel. Jorgenson v. Alan Ritchey, Inc.*, 2007 WL 1287932, at *3 (W.D. Wash. Apr. 27, 2007) (dismissing FCA allegations regarding fraud at company locations other than the one about which the relator asserted insider knowledge because "alleged fraudulent activity at one plant does not constitute an allegation for a different plant").

Finally, in all events, these discrete incidents all occurred after August 2012, and accordingly, they cannot provide a factual basis to plead intent during the time period from 2010 through August 2012. "'[T]here is no fraud by hindsight.'" *United States ex rel. United Union of Roofers, Waterproofers & Allied Workers Local No. 11 v. City of Chicago*, 2014 WL 6306582, at *4 (N.D. Ill. Nov. 12, 2014) (quoting *United States ex rel. Garst v. Lockheed–Martin Corp.*, 328 F.3d 374, 378 (7th Cir. 2003)); *see also United States ex rel. Phalp v. Lincare Holdings, Inc.*, 116 F. Supp. 3d 1326, 1359 (S.D. Fla. 2015) (where "the last exemplar transaction at issue was initiated in May 2009," purported evidence of intent from "October 2009" could not suffice; "Relators do not explain how an October email would allow a

reasonable jury to conclude that [Defendant] knowingly submitted false claims in May of the same year"), *aff'd as modified*, 857 F.3d 1148 (11th Cir. 2017).

II. THE COMPLAINT DOES NOT STATE A "REVERSE" FALSE CLAIM

The Government's separate "reverse false claim" theory is defective for all of the same reasons discussed above. It should also be dismissed for the independent reasons that (1) a reverse-FCA claim cannot be based upon duplication of an affirmative-FCA claim; and (2) the Government fails to allege any independent payment "obligation."

A. The Reverse-FCA Claim Duplicates the Affirmative-FCA Claim.

The Government bases its reverse-FCA claim entirely on the allegations underlying its affirmative-FCA claim, suggesting that Omnicare was obligated to return the funds allegedly obtained "for dispensing prescription drugs that were not authorized by valid prescriptions." *Id.* ¶ 285. In so doing, the Government assumes that the presentment of allegedly false claims can trigger liability twice: first, under § 3729(a)(1)(A), upon the submission of the request, then again under § 3729(a)(1)(G), by virtue of not returning the alleged overpayments for the allegedly false claims. This theory has been resoundingly rejected.

"Congress' purpose in enacting subsection (a)(7)[10] was to ensure that one who makes a false statement in order to avoid paying money owed the government 'would be equally liable under the Act as if he had submitted a false claim to receive money'"; its purpose was "not to provide a redundant basis to state a false statement claim." *United States ex rel. Thomas v. Siemens AG*, 708 F. Supp. 2d 505, 514 (E.D. Pa. 2010) (quoting S. Rep. No. 99-345, at 18 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5283). Courts have rejected arguments that allegations regarding the submission of false claims or making of false statements to get claims

[10] Prior to 2009, the reverse-FCA provision was § 3729(a)(7) rather than § 3729(a)(1)(G).

paid may be recast as reverse false claims solely because a defendant failed to return the money obtained via the allegedly false claim for payment. *See, e.g.*, *United States v. Mount Sinai Hosp.*, 256 F. Supp. 3d 443, 457 (S.D.N.Y. 2017) (agreeing with prior S.D.N.Y. ruling "that allegations stating a claim under 31 U.S.C. §§ 3729(a)(1), (2) cannot also form the basis for a claim under subsection (a)(7)"). Otherwise, "'just about any traditional false statement or presentment action would give rise to a reverse false claim action.'" *Mount Sinai Hosp.*, 256 F. Supp. 3d at 458 (quoting *Pencheng Si v. Laogai Research Found.*, 71 F. Supp. 3d 73, 97 (D.D.C. 2014)).[11]

B. The Government Does Not Identify Any "Overpayment" Obligation.

The Government's failure to allege anything but a redundant recitation of its affirmative-FCA claim is no mere technicality. Rather, it means that the Government does not allege any of the specific elements of a reverse-FCA claim: "(1) that the defendant had an obligation to pay money to the government, (2) that the defendant used a false statement to avoid or decrease that obligation, (3) that the false statement was material, and (4) that the defendant made the false statement knowingly." *Davern*, 2015 WL 6872427, at *9 (internal quotation marks omitted). Absent any allegation about a "clear" obligation to return money to the government, *United States ex rel. LaPorte v. Premier Educ. Grp., L.P.*, 2016 WL 2747195, at *18 (D.N.J. May 11, 2016), Omnicare is left to guess what independent payment obligation it is alleged to have had, what false statements it is alleged to have made, and how such unidentified statements could have been material or been made knowingly. *See also Kester*, 43 F. Supp. 3d at 368 ("Where a complaint 'makes no mention of any financial obligation that the defendants owed to the government," and 'does not specifically reference any false records or statements used to

[11] *United States ex rel. Kester v. Novartis Pharms.*, 2015 WL 109934 (S.D.N.Y. Jan. 6, 2015), is not to the contrary. There, this Court rejected a duplication argument because the defendants "have not argued for dismissal of [the reverse-FCA claim] except for the same reasons that they argue" against the affirmative-FCA claims. *Id.* at *24.

decrease such an obligation,' the court should dismiss the subsection (a)(1)(G) claim." (quoting *United States ex rel. Wood v. Applied Research Assocs., Inc.*, 328 F. App'x 744, 748 (2d Cir. 2009))).

The Government's reverse-FCA claim omits any legal or factual support for the contention that the conduct underlying the alleged affirmative-FCA claims somehow created an obligation that Omnicare "repay the Government Payors the payments Defendants had received for dispensing prescription drugs that were not authorized by valid prescriptions." Gov't Compl. ¶ 285; *see also id.* ¶ 233 (alleging that Defendants "received tens of millions of dollars in Federal Healthcare Program payments for dispensing these drugs without valid prescriptions," which "constituted overpayments from Federal Healthcare Programs"). Omnicare's hypothetical liability for the affirmative-FCA claims brought in this same case is a "contingent obligation[]" that cannot form the basis for reverse-FCA liability. *Am. Textile Mfrs. Inst. v. Ltd.*, 190 F.3d 729, 738 (6th Cir. 1999).

To be sure, the Government briefly alludes elsewhere in the Complaint to the general process by which Medicare and Medicaid engage in "reconciliation." Gov't Compl. ¶¶ 24, 32, 48. But the statutory provision on which the Government relies defines "overpayment" narrowly: "[F]unds that a person receives or retains under subchapter XVIII [governing Medicare] or XIX [governing Medicaid] to which the person, ***after applicable reconciliation***, is not entitled under such subchapter." 42 U.S.C. § 1320a-7k(d)(4)(B) (emphasis added). Reverse-FCA claims are dismissed where, as here, "there is no allegation that any such 'reconciliation' occurred." *United States ex rel. Martino-Fleming v. S. Bay Mental Health Ctr.*, 2018 WL 4539684, at *6 (D. Mass. Sept. 21, 2018). The Government does not allege the existence of any "applicable reconciliation" involving Omnicare, far less one that resulted in the identification of

a specific overpayment that Omnicare avoided.[12] In fact, the Government merely describes the "reconciliation" that is done not by Omnicare, but by Medicare Part D Plans and State Medicaid agencies. *See* Gov't Compl. ¶¶ 32, 48.

III. THE COMPLAINT DOES NOT STATE A CLAIM FOR UNJUST ENRICHMENT OR PAYMENT BY MISTAKE

In addition to its various FCA claims, the Government pleads tersely stated claims for "Payment by Mistake of Fact" and "Unjust Enrichment," both apparently arising from the same set of facts that undergird its FCA allegations. *Id.* ¶¶ 287–292. The Government is silent as to its theory of how it made mistaken payments or how Omnicare was unjustly enriched. These theories fail for the reasons the FCA claims do, but they also should be dismissed for three independent reasons:

First, the Government does not make clear which state law(s) it invokes regarding unjust enrichment and payment by mistake. *See United States ex rel. St. Joseph's Hosp., Inc. v. United Distribs., Inc.*, 918 F. Supp. 2d 1306, 1316 (S.D. Ga. 2013) (dismissing claims where "it is unclear from the complaint whether the Government's claims of unjust enrichment and payment by mistake were pled under federal common or Georgia state law").

Second, if the Government intends to invoke federal law, its claims of unjust enrichment and payment by mistake do not exist. Such theories trace their roots to a Supreme Court decision from the 1930s—"the era of rampant federal common law that Erie brought to an end." *Powers v. U.S. Postal Serv.*, 671 F.2d 1041, 1043 (7th Cir. 1982); *see United States v. Wurts*, 303 U.S. 414 (1938). In *Wurts*, the Supreme Court crafted a federal-common-law claim, "independent of statute," allowing the Government to "recover funds which its agents have wrongfully,

[12] The Complaint alleges three "overpayments" in connection with resolved third-party audits of Omnicare. *See* Gov't Compl. ¶¶ 203–205. But there is no allegation that Omnicare wrongly retained any of the overpayments identified during those audits.

erroneously, or illegally paid" in connection with an erroneous tax refund. *Id.* at 415; *see also United States v. Domino Sugar Corp.*, 349 F.3d 84, 88 (2d Cir. 2003) (citing *Wurts* for a claim related to taxes).

Modern law is entirely to the contrary. "Common-law doctrines yield to statutes," *Pierce v. Visteon Corp.*, 791 F.3d 782, 787 (7th Cir. 2015), and "[t]here is no federal general common law," *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938). "When Congress addresses a question previously governed by a decision rested on federal common law, . . . the need for such an unusual exercise of law-making by federal courts disappears." *Am. Elec. Power Co. v. Connecticut*, 564 U.S. 410, 423 (2011) (brackets and internal quotation marks omitted). Congress may accomplish this by specifically describing the remedies available to the Government under federal statutes. *See Lummi Tribe of Lummi Reservation v. United States*, 106 Fed. Cl. 623, 625 (2012) ("Congress, by setting forth the remedies available to HUD under this title, expressed its intention to bar all other remedies."); *accord Alexander v. Sandoval*, 532 U.S. 275, 290 (2001) ("The express provision of one method of enforcing a substantive rule suggests that Congress intended to preclude others."). Congress has laid these requirements out, in detail, in the Medicare and Medicaid laws the Government purports to enforce.

Third, even if the Government's federal common law theories exist, their use would be appropriate "only if no adequate legal remedy exists." *United States v. Job Res. for Disabled*, 2000 WL 562444, at *4 (N.D. Ill. May 9, 2000). Here, however, the FCA itself is "an adequate legal remedy to protect the federal government's interests." *Id.*; *accord United States v. Hydroaire, Inc.*, 1995 WL 86733, at *6 (N.D. Ill. Feb. 27, 1995).

CONCLUSION

For the foregoing reasons, the Government's Complaint-in-Intervention should be dismissed.

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Respectfully submitted,

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